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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,893	12/01/2000	Dennis Bigg	427 038	9852
20311	7590	04/21/2004	EXAMINER	
MUSERLIAN AND LUCAS AND MERCANTI, LLP 475 PARK AVENUE SOUTH NEW YORK, NY 10016			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/701,893	BIGG ET AL.
	Examiner Brenda Coleman	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 January 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 3,4 and 9-13 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 3,4 and 9-13 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 3, 4 and 9-13 are pending in the application.

This action is in response to applicants' amendment filed January 21, 2004.

Claims 4 and 9-12 have been **amended**.

Response to Arguments

Applicants' arguments filed January 21, 2004 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 102, anticipation rejections labeled 4 and 8 maintained in the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

4) The applicants' stated that disclaimer iiii(iii) properly excludes R'₁ as being o-chlorine as being o-chlorine since it has been changed to para-chlorine.

However, the disclaimer labeled iiii(iii) is such that there is no limitation to R'₁ and thus the rejection of claim 11 as being anticipated by Girault where R is para-chloro is herein maintained.

Claim 11 is rejected under 35 U.S.C. § 102(b) as being anticipated by Girault et al., Chromatographia, for reasons of record and stated above.

8) The applicants' stated that the disclaimer iiii), X is now defined as being – CH₂- and not ethylene. The disclaimer iiii) is such that X' is CH₂-, Y' is oxygen, R'₁ is p-chlorine and R_{2a}' and R_{2b}' are hydrogen, R'₃ is methyl and R' is phenyl or 4-fluoro-phenyl. However, the compounds taught by Okano is where W is 4-fluorophenyl-CH₂-C(O) and phenyl-CH₂-C(O) and R'₁ is o-chloro, which is not

excluded by the proviso of claim 11 and thus the rejection of claim 11 as being anticipated by Okano is herein maintained.

Claim 11 is rejected under 35 U.S.C. § 102(b) as being anticipated by Okano et al., EP 0 367 110, for reasons of record and stated above.

2. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections of claim 13, labeled paragraph 5) maintained in the last office, which are hereby **withdrawn**.

3. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejections of claims 9-11, labeled paragraph 6) of the last office, which are hereby **withdrawn**.

4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled a), c), d), e), g), h), j), k), l), m), n), o), p), q), r), s), t), u), v), w), y), z), aa), ab), ac), ad), ae), af), ag), ah), ai) and aj) of the office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled b), f), i) and x) the applicant's amendments and remarks have been fully considered but they are not persuasive.

b) The applicants' stated that a new formula has been inserted to obviate the rejection in paragraph b). However, the rejection labeled paragraph b) is on the basis that there is no definition in the claim for the variable R'3.

Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

f) The applicants' stated that with respect to paragraph f), R_3 has been changed to R'_3 . However, the rejection labeled paragraph f) is on the basis that the variable R'_3 in the proviso labeled ii) is not R prime subscript 3, i.e. R'_3 , but rather R subscript prime three, i.e. R_3 .

Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

i) The applicants' stated that with respect to paragraph I), the missing hyphen has been inserted into claim 11. However, this is not so.

Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

x) The applicants' stated that regarding paragraph x), it has been corrected. However, this is not so.

Claim 10 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

5. With regards to the 35 USC § 103, obviousness rejection of claim 11 by Okana et al., EP 0 367 110 of the last office action, the applicants stated that it is believed that the present disclaimer excludes compounds wherein W is 4-fluoro-phenyl-CH₂-C(O)- and phenyl-C(O)-. However, as pointed in the response to the 102 by Okana stated above. The disclaimer is not sufficient.

Claim 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Okana et al., EP 0 367 110, for reasons of record and stated above.

6. With regards to the 35 USC § 103, obviousness rejection of claim 11 by Braquet et al., FR 2 660 311 of the last office action, the applicants believed that the claims clearly distinguish from this reference and that the applicants' invention is directed to the use of diazepines having an affinity for somatostatin receptors is involved. However, the motivation to make the compounds is "the reference" in and of itself. The use of the compounds in the reference is irrelevant with respect to the compound claims of the instant invention.

Claim 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Braquet et al., FR 2 660 311, for reasons of record and stated above.

7. With regards to the 35 USC § 103, obviousness rejection of claim 11 by Weber et al., EP 0 503 471 of the last office action, the applicants believed that the claims clearly distinguish from this reference and that the applicants' invention is directed to the use of diazepines having an affinity for somatostatin receptors is involved. However, the motivation to make the compounds is "the reference" in and of itself. The use of the

compounds in the reference is irrelevant with respect to the compound claims of the instant invention.

Claim 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Weber et al., EP 0 503 471, for reasons of record and stated above.

In view of the amendment dated January 21, 2004, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 11 is rejected under 35 U.S.C. 1 12, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the invention, at the time the application was filed, had possession of the claimed invention. The amendment to the proviso labeled ii)) where R'1 is p-chloro and not o-chloro is not described in the specification.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 4, 9, 10, 11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 4 is vague and indefinite in that it is a duplicate of claim 3.
- b) Claim 9 is vague and indefinite in that it is not known what is meant by the definition of Z where Z is selected from the group **consisting a** covalent bond....
- c) Claim 10 is vague and indefinite in that it is not known what is meant by hypopyseal.
- d) Claim 11 is vague and indefinite in that it is not known what is meant by the compounds of formula II. There is no indication of a formula II in the claim.
- e) Claim 11 recites the limitation "o-chlorine" in the definition of R'₂. There is insufficient antecedent basis for this limitation in the claim.
- f) Claim 13 recites the limitation "R_{2a} and R_{2b}" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim.
- g) Claim 13 contains several species which are excluded by proviso, i.e. the ninth species on page 10 and the twenty fourth, twenty seventh, twenty ninth and thirtieth species on page 12.
- h) Claim 13 recites the limitation "formula II" in the claim. There is insufficient antecedent basis for this limitation in the claim.
- i) Claim 13 recites the limitation "W" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Objections

10. Claims are objected to because of the following informalities:

- a) Claim 4 contains four moieties in the definition of X which are missing the bonds to indicate the point of attachment as is shown by two of the moieties -O- and -S-.
- b) Claims 9, 10 and 12 contain a moiety, which are missing a bond to indicate the point of attachment, i.e. $Z_{32}R_{34}$.
- c) Claims 9 and 10 contain a moiety in the definition of Z_{32} , which is missing a bond to indicate the point of attachment, i.e. $-SO_2$.
- d) Claim 11 contains in several occurrences the moieties chlorine, fluorine and bromine which are not substituents but compounds in themselves. (See lines 5, 11, 12, 20, 22 and 23 on page 8 and line 3 of page 9 of the amendment)
- e) Claim 11 contains a moiety in the definition of X' which is missing a bond to indicate the point of attachment, i.e. $-CH_2-CH_2$.

Appropriate correction is required.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Brenda Coleman
Primary Examiner Art Unit 1624
April 19, 2004